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Clinical Trials:
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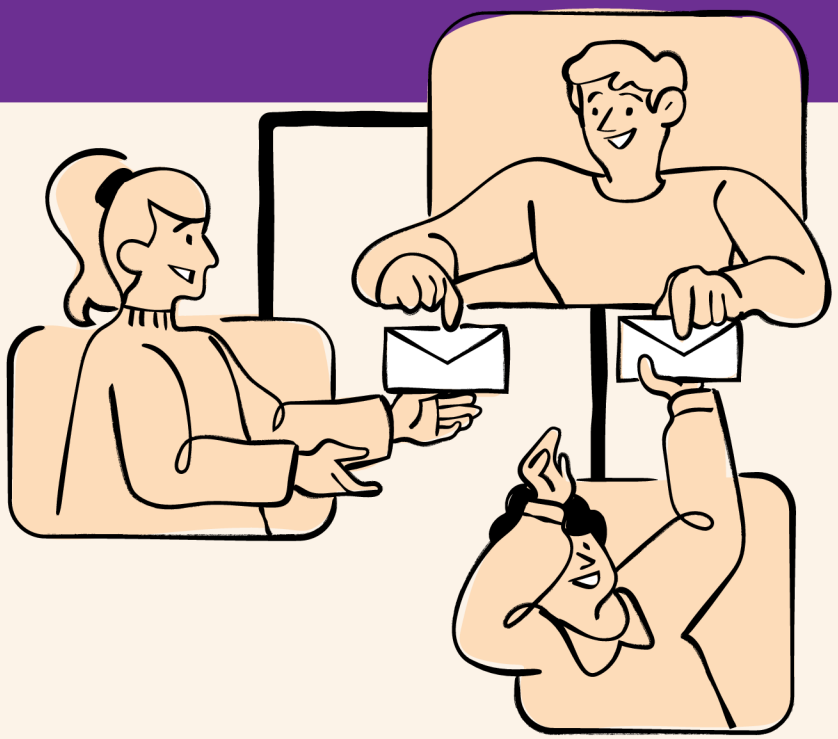
Ethics Submission and Review Guide for Clinical Trial Data Sharing



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Australian Research Data Commons

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Acknowledgement of Country

CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

The CT:IQ/ARDC Clinical Trials Data Sharing Frameworks Project

Under the Clinical Trial Data Sharing Frameworks project, ARDC and CT:IQ have developed a set of resources to support high-quality and efficient clinical trial data sharing decisions by Australian researchers, human research ethics committees (HRECs), and institutions. Available resources include:

- A Data Sharing Toolkit, which provides high-level information on data sharing governance designed for those newer to the space. The Toolkit covers the full lifecycle of clinical trial data sharing activities from project design through to data retention and destruction.
- An Ethics Submission and Review Guide, which provides researchers (data providers and data recipients), ethics review body members and others with guidance on the requirements for ethics review of clinical trial data sharing applications under the NHMRC National Statement on Ethical Conduct in Human Research (2025) and other relevant laws and guidelines.
- A Responsibilities for the Secondary Sharing of Clinical Trial Data in Australia (‘Governance Framework’), which provides detailed information on the application of specific Australian laws and regulations relevant to clinical trial data sharing. The Governance Framework is designed to act as a point of reference for more detailed queries about legal and regulatory responsibilities.
- A Data Glossary to provide a shared set of definitions for words relevant to clinical trial data sharing.

1. Introduction

The National Health and Medica Research Council (NHMRC) *National Statement on Ethical Research Involving Humans* (2025) ('National Statement') requires ethics review of all research involving humans, which is defined as 'research conducted with or about people, or their data or their biospecimens'. This will include sharing clinical trial data for research purposes, including where personal identifiers have been removed from the data.

This Guide has been developed to support the ethics review process for clinical trial data sharing projects. It explains what ethics review bodies (ERBs), including Human Research Ethics Committees (HRECs) look for when they consider these data sharing projects, and what documents are needed in an application. Following the Guide can help make the review process smoother and faster for researchers and ERBs.

You should read this Guide alongside applicable laws and policies, including the National Statement and relevant privacy laws in your state or territory. Clinical trial data collected by private institutions and Commonwealth government agencies will also need to comply with the Guidelines approved under sections 95 and 95A of the *Privacy Act 1988* (Cth). The Guidelines—in combination with overarching criteria set out in the Act—define the criteria and process for researchers to seek access to personal information without consent. Broadly equivalent guidelines are in place in some Australian states and territories.

Applications for research involving clinical trial data sharing should not be conflated with seeking retrospective approval for research. Seeking delayed or deferred consent to participation or retrospective consent after some or all components of the research have been completed is not ethically permissible, as stated in para 4.5.7 of the National Statement.

2. Understanding the ethical acceptability of research projects using clinical trial data

Solid preparation is key to an efficient and effective ethics review process. Before engaging with an ERB, researchers should undertake the following steps to understand and characterise the ethical acceptability of a data sharing research project.

Both **data providers** (clinical trialists seeking to share datasets) and **data recipients** (researchers seeking to use clinical trial datasets for another research project) should satisfy themselves of the ethical and legal acceptability of a data sharing research project.

2.1 Consider and engage with relevant participant groups

Early engagement with participant and consumer groups is a key enabler for effective and ethical sharing of clinical trial data. Early engagement provides important information about participant and consumer expectations of how their data should be treated. This can improve the protocol design by better aligning it with community needs and expectations. It also can assist with the ethics review process.

Fig 1. Lisa Eckstein and Vanessa Warren, Consultation report on current challenges and practices regarding ethics and governance approval for data sharing (2024)

Engagement with consumers will be especially important for research projects involving data about Aboriginal and Torres Strait Islander people and rare disease groups, as well as for data that may be sent offshore or used for commercial purposes. Guidance on engaging with consumers is available in the ACTA/CT:IQ Consumer Involvement and Engagement Toolkit.

Public views on sharing genomic data: In qualitative research, members of the Australian public have indicated a high willingness to share their genomic information; however, this willingness is dependent on context. Willingness to share is positively impacted by a strong perception of benefits. Concerns that may limit willingness to share include commercial involvement, unknown future uses, and privacy risks.[1]

2.2 Liaise with data custodians and linkage agencies

Data recipients should liaise early with the relevant data custodians and, if relevant, data linkage agencies, to ask if they would be willing to share clinical trial data and under what conditions. For example, a data custodian may require review by an HREC rather than a low-risk ERB. In some circumstances, the data custodian may require review by a specific ERB. Early engagement with the relevant data custodians will also clarify the precise data items available for access. Ultimately, it is the decision of the data custodian/s to determine whether they wish to share data.

While there is considerable variation in which individual or body is given responsibility for data custodianship of a clinical trial dataset, this will commonly be the principal investigator or chair of the study Steering Committee.

2.3 Review any prior consent

Preparation for an ethics submission should include a review of any consent that clinical trial participants have provided for their data to be shared for future research. This includes any promises made to participants in the original trial's Participant Information and Consent Form (PICF). Examples include:

1. **The trial PICF advised that data would not be used for future research and/or would be destroyed at the end of the trial.** This data should **not be used** for future research without specific and express consent for sharing from trial participants.

[1] Warren, Vanessa, et al. "Context matters in genomic data sharing: a qualitative investigation into responses from the Australian public." *BMC Medical Genomics* 15.Suppl 3 (2023): 275.

2. **The trial PICF was silent on the potential for future research.** An application to use this data will require an ERB to review whether data sharing requires **reconsent from trial participants and/or a waiver of the requirement for consent**.
3. **The trial PICF provided for consent (express, extended or unspecified) for future sharing.** An application to use this data will require an ERB to review whether the consent provided is **adequate to support** sharing for the proposed research based on the risks associated with sharing (eg identifiability) and the strength of the original consent. If the PICF is not adequate to support sharing, the ERB will require **reconsent from trial participants and/or a waiver of the requirement for consent.**

Information on how an ERB will make such assessments is provided in section 3.3 of this Guide. The data provider is typically responsible for ensuring that participants have consented to their data being shared for the research project. It is best practice for a data recipient to seek evidence of the ethical acceptability of sharing, including the PICF for the original trial.

The original trial PICF should be included in the ethics application for a data sharing project.

2.4 Develop and comply with a data management plan

To minimise the risks and maximise the benefits of data sharing research projects, data recipients should develop a data management plan. Under paragraph 3.1.44 of the National Statement, data management plans should include:

- Identification of a custodian for the data generated by the research project. Depending on the size of the dataset, this may be a data access committee;
- Information on how data will be generated, collected, accessed, used, analysed, disclosed, stored, retained, disposed of, shared and re-used;
- Processes to ensure physical, network, and system security, including any training for members of the research team; and
- A plan for managing any intellectual property rights resulting from the research.

Data providers should ensure that the data management plan for the original trial supports the proposed data sharing. Where the proposed data sharing activities are not supported by the trial's data management plan, the data provider should consider amending the plan. Amendments to the data management plan may require approval by the relevant institution and/or reviewing ERB.

Many Australian research institutions have template data management plans available. Otherwise, the Australian Research Data Commons gives a number of examples. A copy of the data management plan should be included in the ethics application.

3. Applying for ethics review of a data sharing research project

With very few exceptions, research involving data sharing must be reviewed by at least one ERB. Sometimes, review by more than one ERB is necessary.

While there is no definitive list of when multiple ERBs may be required to review clinical trial data sharing projects, the below is likely to comprise broadly agreed parameters.

- Unless an exemption from review (section 3.4 of this Guide) applies, a data recipient must obtain approval from an ERB before accessing clinical trial datasets. The ERB will assess the overall risk/benefit ratio of the research project, including the proposed methodology and data management plan.
- A data provider may need to get approval from the ERB that oversaw their clinical trial before sharing data. Whether this is required depends on the type of data being shared and the scope of the original ERB approval, including whether the trial's PICF and data management plan clearly provided for data sharing. Usually, if the project already allowed for future data use consistent with the proposed data sharing project, new ERB approval isn't needed; however, the data provider should confirm this with the ERB.
- If access to administrative datasets is being sought for the research project, the data recipient may be required to obtain approval from a specific ERB as a condition of data sharing.

3.1 Contact the relevant ethics review body/ies to confirm their submission requirements

The ERB will be able to advise of their requirements for review, including:

- The standard application form and submission platform
- Required documentation
- Any submission fee
- The availability of low-risk review pathways

Where a research project will be **analysing data about Aboriginal and Torres Strait Islander people and communities**, the research should be reviewed by an ERB with the necessary cultural competence. The ERB will be able to advise of the relevant submission requirements, including evidence of engagement and involvement by Aboriginal and Torres Strait Islander peoples and communities. Researchers should review and address in their submission:

- The values described in the NHMRC *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders and Keeping Research on Track II* (2018);
- The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Code of Ethics for Aboriginal and Torres Strait Islander Research* (2020) and associated guide.

3.2 Assess the research benefits and risks

A key component of ethics review is balancing the benefits of a research project against its risks. **The more clearly the benefits and risks of a research project are articulated, the better equipped ERBs will be to apply the criteria under the National Statement**.

3.2.1 Identify the benefits and risks

When thinking about **benefits**, consider the realistic outcomes of undertaking the research project. These could include additional scientific knowledge, prevention or treatment of disease, delivery of health services, and a lessened need for new clinical trials.

When thinking about **risks**, remember these extend beyond physical harms to include also psychological, cultural, social, economic and legal harms. While data sharing will rarely if ever entail physical harm, other potentially relevant harms include:

- Psychological harm, including feelings of distress, anxiety or re-traumatisation;
- Cultural harm, including misrepresenting or misappropriating cultural beliefs, customs or practices;
- Social harm, including damage to relationships with others; discrimination in access to benefits; or unauthorised disclosure of personal information; and
- Economic harm.

The National Statement advises (Ch 3.1 Element 4) that the risks of data sharing are greatest

> *when the identity of an individual can reasonably be ascertained by reference to an identifier or combination of identifiers. Risk may also arise where identifiers have been replaced by a code but where reidentification remains possible.*

Factors that should be considered in determining a project's risk include:

- the type and quantity of data being shared
- any other information held by the individual receiving the data
- the capacity of the recipient to reidentify the data.

Researchers should also consider the risks of harm that may result to groups or communities from data sharing, for example, through stigmatisation of the group or group members. Particular risks will apply to research with Aboriginal and Torres Strait Islander data, which should always be discussed with relevant peoples and communities.

3.2.2 Describe risk mitigation practices

Chapter 3.1 Element 4 of the National Statement specifies that risks may be mitigated by, among other strategies:

- minimising the number of variables collected
- storing identifiers and content information separately
- separating the roles of those responsible for managing identifiers and those responsible for analysing content.

Additional risk mitigation strategies may include:

- Providing aggregate rather than person-level data where possible.
- Applying privacy-preserving techniques, such as replacing dates of birth with 5-year age groups, or postcodes with a metropolitan/rural category.
- Suppressing small cell sizes.
- Governance controls, such as restricting access and implementing data sharing agreements.

Tip: the Five Safes principles can help researchers to think about the risks of data sharing and describe the risk mitigation strategies they have adopted.[2]

Safe Projects. Whether the data is being used for appropriate purposes and is likely to be in accordance with community expectations.

Safe People. The knowledge, skills and trustworthiness of the researcher.

Safe Data. The disclosure risks inherent in the data being shared.

Safe Settings. The access controls in place, such as use of a trusted research environment.

Safe Outputs. Whether any published results could reveal the identity of individuals.

[2] ABS, 'Five Safes Framework' (2021), available at 'Five Safes Framework' (2021), available at https://www.abs.gov.au/about/data-services/data-confidentiality-guide/five-safes-framework.

Good data management practice can lessen the risk of data sharing:

Good planning and governance practices can be instrumental in lessening risks of sharing patient-level data. This was illustrated in a 2025 Privacy Decision Report into preliminary inquiries of I-MED issued by the Australian Privacy Commissioner. I-Med Radiology is a large diagnostic imaging network. It disclosed medical imaging scans to Annalise.ai, a healthcare AI company. In deciding whether I-Med had breached Australian privacy laws, the Commissioner noted the extensive deidentification practices prior to data being shared.

This included:

- segregating the patient data from the underlying dataset,
- scanning the records with text recognition software,
- using two hashing techniques (for unique identifiers such as patient ID numbers, and names, addresses and phone numbers),
- time-shifting dates (to a random date within a specified number of years),
- aggregating certain fields into large cohorts to avoid identification of outliers, and
- redacting any text that appears within or within 10% from the boundary of an image scan.

I-Med also required Annalise.ai to agree to a range of contractual responsibilities, including a prohibition on reidentification, a prohibition of further disclosing or publishing the data, secure storage practices, and notification of any inadvertent privacy breach. In combination, the Commissioner determined these measures lessened the remaining risk of reidentification to a low enough level that the data could be considered deidentified.[3]

3.2.3 Assess the suitability of lower-risk review pathways

Institutions may establish lower-risk pathways to review research in which there is **no risk of harm**, and the only foreseeable risks are **no greater than discomfort**. Chapter 2.1 of the National Statement lists examples of discomfort as including 'minor side effects of medication, discomfort related to non-invasive examinations or tests (such as measuring blood pressure), and mild anxiety associated with an interview'. Whether a proposed data sharing activity should be considered lower-risk is a case-by-case decision for an institution.

Research that will be analysing data about Aboriginal and Torres Strait Islander people and communities may not be suitable for lower-risk review. This should be assessed by a person or body with the requisite cultural competence in accordance with Chapter 4.7 of the National Statement to ensure that the research is culturally safe, ethical, considered, meaningful and beneficial to Aboriginal and Torres Strait Islander people and communities. Most commonly, this will require assessment by a specialised Aboriginal HREC.

[3] Office of the Australian Information Commissioner, Report into preliminary inquiries of I-MED (31 July 2025), available at https://www.oaic.gov.au/privacy/privacy-assessments-and-decisions/privacy-decisions/Investigation-inquiry-reports/report-into-preliminary-inquiries-of-i-med

3.3 Provide evidence of consent for sharing or justify a waiver of the requirement for consent.

3.3.1 Consent for sharing

Wherever possible, clinical trial data should only be shared for future research with the consent of trial participants. Under para 2.2.14 of the National Statement, consent can take three forms:

- **Specific consent:** A participant has agreed for their data to be shared for the purposes of a specific research project. This consent provides a solid legal and ethical basis to support data sharing.
- **Extended consent:** A participant has agreed to share data for certain kinds of future research. This consent requires an ERB to assess whether a future research project is within the scope of the consent provided, and whether the information provided to trial participants was sufficiently clear and specific to support the proposed sharing. The threshold will be higher for sharing identifiable as compared with deidentified data.

Example: A participant in a diabetes clinical trial consented to their data being shared for research 'related to this condition'. An application is submitted to share their data for a project on cardiovascular disease. An ERB will need to assess whether cardiovascular disease is sufficiently related to diabetes research to fall within the scope of the consent provided. Researchers can assist in this process by providing clear and comprehensive information about the links between the disease areas, including underlying mechanisms and shared risk factors.

- **Unspecified consent:** A participant has agreed to share their data for a wide range of future research projects. The use of this participant's data may be subject to certain limits, for example, that the research project is approved by an Australian HREC and/or that any data shared has had the identifiers removed. To support data sharing, participants must have been made aware of the terms of an unspecified consent and its wide-ranging implications. Provided these conditions have been satisfied, unspecified consent can meet the ethical requirements for many data sharing activities. However, unspecified consent may not be legally sufficient to support sharing identifiable information under privacy laws, including for data linkage activities. Legal advice should be sought before sharing identifiable data based on unspecified consent.

Data providers should consult with their reviewing ERB and institution to ensure that the consent provided by trial participants is sufficient to support data sharing for the proposed research project. Where the original consent a participant provided for the trial is not sufficient to support data sharing, the data provider should seek participant consent for the proposed sharing activity (in this document, described as 'reconsent').

Where possible, the data recipient should include the PICF/s from the trial/s from which data is being sourced with the ethics application, along with an explanation of how consent preferences are being respected (e.g., if participants were given a choice about data sharing, that data will only be shared for those participants who provided such consent).

3.3.2 A waiver of the requirement for consent

In some instances, researchers will seek to collect or disclose data in the absence of consent from trial participants. For any such research, an ERB must authorise a waiver of the requirement for consent in accordance with the criteria set out in paragraph 2.3.10 of the National Statement. **Evidence of the waiver should be in place before a data recipient collects, or a data provider discloses, any clinical trial data for which participants haven't consented to sharing**.

Decisions to authorise a waiver of the requirement for consent for the use of personal information in medical research, or for the use of personal health information, must be made by an HREC rather than through a lower-risk pathway (NS 2.3.9). Decisions about waiving the requirement for consent for the use of other data may be made by any ERB, including low-risk bodies.

Sharing personal information in medical research, or personal health information without consent will also need to comply with applicable privacy law requirements. The applicable privacy laws will depend on the type of data being collected and the laws to which the researcher collecting the clinical trial data are subject. For example, clinical trial data collected by private institutions and Commonwealth government agencies will need to comply with the Guidelines approved under sections 95 and 95A of the *Privacy Act 1988* (Cth). Some Australian states and territories have introduced equivalent frameworks. More information on relevant laws and guidelines is available in the Governance Framework.

Learn about how Australian ERBs reviewed a hypothetical application seeking a waiver of the requirement for consent

Criteria for waivers of the requirement for consent set out in paragraph 2.3.10 of the National Statement

(a) Involvement in the research carries no more than low risk to participants. This means that the only foreseeable risks from the research must be no greater than discomfort. (For research that is required to satisfy the ss 95/9A Privacy Guidelines or relevant State-based guidelines, the potential harms must be minimal.) To assess the risk, it is necessary to consider sensitivity of the data being sought, and strategies being adopted through study design and other measures to minimise the likelihood of harm. The Five Safe principles discussed in section 3.2.2 will assist with this task.

(b) The benefits from the research justify any risks of harm associated with not seeking consent. For research that is required to satisfy the ss 95/9A Privacy Guidelines or relevant State-based guidelines, the public interest in the research must outweigh, to a substantial degree, the public interest in complying with the privacy principles). Consider the public health interests in the future research, the financial and other costs of not undertaking the research, and any benefits of the research to participants or the class of persons to which they belong. Harms may include privacy risks to individuals, loss of trust in healthcare providers, and stigmatisation of groups to which participant belong.

(c) It is impracticable to reconsent trial participants. The National Statement explains that this may be due to the quantity, age or accessibility of records. There is no bright dividing line as to when seeking reconsent might not be practicable; however, ERBs are likely to consider:[4]

- Whether obtaining reconsent would place undue hardship on researchers due to, e.g., the sample size or incompleteness of contact information
- Whether obtaining reconsent would invalidate the study outcomes, e.g., due to selection bias
- Whether obtaining reconsent would harm the participant or others, e.g., by violating privacy or inflicting psychological, social or emotional harm as may be the case where trial participants are deceased or incapacitated

The impracticability of seeking reconsent should be distinguished from mere inconvenience.

(d) There is no known or likely reason for thinking that participants would not have consented if they had been asked. Consider how similar or different the future research project is from the original project to which participants consented. Are there any additional considerations relating to the nature of the research that may be relevant to participant willingness to consent? This may include sharing with industry, or across country borders.[5]

(e) There is sufficient protection of their privacy and (f) an adequate plan to protect the confidentiality of data. This information should be available in the data management plan.

(g) Where results have significance for the participants' welfare there is a plan for making information arising from the research available to them. There is an ethical imperative to share research results with participants, including for research projects. However, the nature of the research will affect whether individual or aggregate results should be made available, and the appropriate means of distributing the results. For example, for research with data from a large number of people, suitable disclosure strategies may include institutional newsletters and relevant consumer groups. It may sometimes be appropriate for participants to be notified directly about the results of research, however, this will need to be weighed against any additional participant risks, for example, if contacting participants to share results requires researchers to collect additional personal information.[6]

[4] Laurijssen, Sara JM, et al. "When is it impractical to ask informed consent? A systematic review." Clinical Trials 19.5 (2022): 545-560.
[5] Critchley, Christine, Dianne Nicol, and Margaret Otlowski. "The impact of commercialisation and genetic data sharing arrangements on public trust and the intention to participate in biobank research." Public health genomics 18.3 (2015): 160-172.
[6] See discussion in Morain, Stephanie R., et al. "Ethical considerations for sharing aggregate results from pragmatic clinical trials." Clinical Trials 22.2 (2025): 248-254.

(h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled. Given the difficulties for participants in asserting property rights over their health data, this criterion is unlikely to be relevant for most data sharing projects.[7]

(i) The waiver is not prohibited by state, federal or international law. Consider any additional legal frameworks that may apply to the information, including the common law duty of confidentiality,[8] and any relevant statutory authorisations for release of a data collection.[9]

[7] Liddell, Kathleen, David A. Simon, and Anneke Lucassen. "Patient data ownership: who owns your health?." Journal of Law and the Biosciences 8.2 (2021): lsab023.
[8] Adams, Carolyn, Annette Braunack-Mayer, and Felicity Flack. "Access to general practice data for research in Australia: the need for greater clarity in relation to privacy and confidentiality." Journal of Law and Medicine 31.4 (2025): 840-855.
[9] Adams, Carolyn, Judy Allen, and Felicity Flack. Sharing linked data for health research: toward better decision making. Cambridge University Press, 2022.

3.4 Exempting clinical trial data sharing from ethics review

In a small number of instances, data sharing projects may be exempt from review by an ERB. The National Statement allows institutions to exempt research from ethics review if it meets the criteria set out in para 5.1.17. The below information is intended to help inform data recipients and institutions on when a research project using clinical trial data may be exempt from review, noting the decision is that of the reviewing institution.

1. **Does the research involve the use of personal information without consent? If so, the research cannot be exempt from review (NS 5.1.16)**

> **Tip:** Participant-level clinical trial data will often constitute personal information, even when it is stored or shared without individual identifiers.

2. **Does the research involve the use of clinical trial data that is stored in a form that can identify individuals? If so, the research cannot be exempt from review (NS 3.1.61)** This includes the use of identifiable clinical trial data for which participants have provided consent for future use.

3. **Does the research carry a lower risk to participants or the community AND meet the requirements set out in para 5.1.17 of the National Statement)? If so, it may be exempt from review, provided the data do not fall within the definition of 'personal information' under applicable privacy laws.**

   To be considered 'lower risk', the only foreseeable risk of the research must be no greater than discomfort. Research in which the risk for participants or others is greater than discomfort (eg, distress) is not low risk research. (See section 3.2.3)

   In addition—to satisfy granting an exemption from ethics review—the research must involve:

   - The removal of all personal identifiers from the data before being received by researchers
   - An agreement by all researchers not to attempt to reidentify any individual with whom the data is associated; to take all reasonable steps to prevent reidentification by others; and to prevent any risks of reidentification from any future data sharing.

Risks associated with information from which identifiers have been removed: A contextual approach will be important when considering potential privacy risks associated with information from which identifiers have been removed. This was highlighted in the 2019 Office of the Victorian Information Commissioner (OVIC) Disclosure of Myki travel information determination, which was about the release by Public Transport Victoria of a linked unit-level dataset containing 1.8 billion records of 'touch on' and 'touch off' activity of more than 15 million Myki cards used over a three year period. Although the dataset technically contained no identifying information, users could be identified based on the knowledge of some trips that they had taken. By finding these known trips, all other trips that used the same card could be identified. The OVIC advised that the definition of personal information should be interpreted contextually, rather than through a strictly literal and technical approach.

Tip: Personal identifiers will include, for example, a person's name, address, telephone number, Tax File Number or other directly identifying information.

Tip: Given the recognised privacy risk even with seemingly de-identified datasets, it is recommended that ethics review is the default expectation for **all proposed sharing of participant-level clinical trial data.**